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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,037	10/21/2003	John F. McEntee	10004031-23	7537

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EXAMINER

AFTERGUT, JEFF H

ART UNIT PAPER NUMBER

1733

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/691,037

**Applicant(s)**

MCENTEE, JOHN F.

**Examiner**

Jeff H. Aftergut

**Art Unit**

1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Maronian et al.

Maronian suggested that it was known at the time the invention was made to form a self-healing rubber article for a medical device. While the reference did not expressly state that the material was a septum, a septum is merely a dividing wall or membrane and the discussion of the use of the article to contain contaminated fluids in the reference at column 1, lines 33-41 appears to suggest that the rubber article of Maronian et al was merely a membrane for containing a fluid in a medical device). The reference taught taking a first resilient layer 10 and stretching the same to place it in tension as indicated by arrows 11. The reference then taught that one would have applied and bonded a first layer of resilient material 12 at the interface 13 between the layers while the layer 10 was in the tensioned condition. The reference suggested that the finished laminate was self-healing from penetration of small needles and the like, see column 2, lines 35-68.

It should be noted that both layers in the reference are resilient as identified above and in reference to claim 15.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art or McKinney further taken with Maronian et al and Jacobs.

The admitted prior art or McKinney suggested that it was known at the time the invention was made to form a three layer septum which included a central rubber layer and two exterior rubber layers which were bonded together to form a laminate for the septum. The references failed to teach that those skilled in the art would have bonded the layers together while the exterior layers were in tension in order to provide the core in compression. It should be noted that the admitted prior art as characterized on pages 1-2 of the specification appears to suggest that the core was held in compression in the finished assembly.

The reference to Maronian suggested in the manufacture of a self sealing laminate that one skilled in the art at the time the invention was made would have provided a layer in compression by joining a layer of elastomeric resilient material to the same while one layer was in tension and then allowed the same to relax (which placed the other layer in compression). The reference taught taking a first resilient layer 10 and stretching the same to place it in tension as indicated by arrows 11. The reference then taught that one would have applied and bonded a first layer of resilient material 12 at

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the interface 13 between the layers while the layer 10 was in the tensioned condition. The reference suggested that the finished laminate was self-healing from penetration of small needles and the like, see column 2, lines 35-68. Clearly, one skilled in the art at the time the invention was made would have desired to incorporate a compression layer in the assembly and a suitable means for forming the same would have been understood to have been to hold one of the layers in tension followed by joining the tensioned layer to the other layer intended to be placed in compression. Since the admitted prior art as well as McKinney provided a three-layer assembly with a central layer in compression, it would have been within the purview of the ordinary artisan that the exterior layers were the ones which were tensioned in the bonding operation in order to provide for compression in the central layer. It further evidence that one skilled in the art at the time the invention was made would have incorporated a tension layer with a core layer there between wherein the tension layers were put in tension during the bonding operation, the reference to Jacobs is cited.

Jacobs suggested that those skilled in the art at the time the invention was made would have provided a core of elastomer material and on either side of the same provided a reinforcing material 4, 5 which was placed in tension and bonded to the core material 2 in the formation of a composite sheet material which was capable of tolerating impingement by particulate material. The use of the tension layers on either side of the core material provided one with the ability to improve the strength of the overall laminate and lessen the risk the laminate becomes cut or torn in processing. As such, it would have been understood that provision of tension, prestressed layers on

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either side of the core would have provided a laminate with enhanced strength and greater resistance to tearing and/or breaking. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the processing of Maronian in the process of making a three layer septum as taught by either one of the admitted prior art or McKinney wherein the bonding takes place subsequent to stretching the exterior layers as taught by Jacobs.

With respect to claim 17, note that the tension was applied in Maronian prior to the bonding operation as well as in Jacobs. Regarding claim 19, note that the tension was applied by stretching the layers, i.e. pulling the same, prior to the bonding operation in both of Jacobs and Maronian. Regarding claim 19, one skilled in the art would have understood that thermal shrinking was a well known equivalent to provision of prestressing in the art of elastomeric materials (for example in the art of elastics it was well known to apply the elastics in a tensioned state or to apply in an untensioned state and follow this with thermal shrinkage to render the elastics elastic in the finished assembly). The use of thermal shrinkage as an alternative to stretching is taken as well known and conventional and would have been viewed as an alternative technique in the art. Regarding claims 20 and 25, note that the references all suggested that the core layer was placed in compression. One skilled in the art at the time the invention was made would have determined the extent of the compression necessary through routine experimentation in order to achieve the desired self sealing effects needed for the septum and such would have included the specified amounts of tension and/or compression. Regarding claims 21 and 22, the references all suggested that the three

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layers would have been formed from elastomeric materials like silicone rubber.

Regarding claim 23, the references to Maronian and McKinney suggested a thickness for the finished laminate of less than 10 mm in thickness and thus each layer making up the laminate must be less than 10 mm in thickness. Regarding claim 24, note that the core layer was clearly placed in compression. Regarding claim 26, note that compression via core expansion would have been viewed as a functional equivalent to thermal shrinkage of the exterior layers. Such thermal expansion of a layer is taken as conventional in the art and it would have been within the purview of the ordinary artisan to provide such thermal expansion in order to form the laminate wherein the central layer was in compression.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It would appear that claim 26 is misplaced. In order for the core to be in compression (which was desirable in the finished assembly), the core layer would have had to have been subjected to thermal expansion and not the "third layer" as claimed. It is suggested that on line 3 of claim 26 the "third layer" be changed to --first layer-- to more clearly and concisely claim the invention in a manner which can be understood.


**Conclusion**

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller teaches the use of compression in a septum in order to render the same self-healing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff H. Aftergut whose telephone number is 571-272-1212. The examiner can normally be reached on Monday-Friday 7:15-345 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeff H. Aftergut  
Primary Examiner  
Art Unit 1733

JHA  
February 21, 2006